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EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	**PAPER NUMBER**
1637	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,690	BYRD ET AL.	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-98* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 37, 38, 60-66 and 98, drawn to an isolated nucleic acid molecule engineered to comprise all or a portion of at least two Ter sites, wherein the nucleic acid comprises an origin of replication and the Ter sites are arranged with respect to the origin of replication such that the sequence between the two Ter sites is not replicated, classified in class 536, subclass 23.1, for example.

II. Claims 10-15, 20-22, 47-52, drawn to a modified Ter-binding protein, classified in class 530, subclass 350, for example.

III. Claims 16-19, 88-90, drawn to a support comprising at least one oligonucleotide that comprises all or a portion of a Ter site, classified in class 435, subclass 287.1, for example.

IV. Claims 23-27, drawn to a method for directional cloning comprising: providing a nucleic acid molecule comprising one or more Ter sites or portions thereof; providing a vector molecule comprising one or more Ter sites or portions thereof; inserting the nucleic acid molecule into the vector molecule; and selecting the vector molecule comprising the nucleic acid molecule in the desired orientation, classified in class 435, subclass 6, for example.

V. Claims 28-30, 53-59, drawn to a method for attaching nucleic acid to a solid support, comprising: attaching all or a portion of one or more Ter-binding proteins to a solid support; and contacting the Ter-binding protein with a first nucleic acid, said nucleic acid comprising a Ter site,classified in class 435, subclass 7.1, for example.

VI. Claims 31-36, drawn to a method of improving the transfection efficiency of a nucleic acid molecule, comprising: providing all or a portion of one or more Ter site in the nucleic acid molecule; and contacting the nucleic acid molecule with all or a portion of one or more Ter-binding proteins, classified in class 435, subclass 7.1, for example.

VII. Claims 39-41, drawn to a method for improving the stability of a linear nucleic acid molecule in vivo, comprising: providing a linear nucleic acid molecule, the nucleic acid molecule comprising all or a portion of one or more Ter sites; contacting the nucleic acid molecule with all or a portion of one or more Ter-binding proteins to form a stable nucleic acid-protein complex; and introducing the stable nucleic acid-protein complex into a host cell, wherein the complex is more stable than the nucleic acid transfected alone, classified in class 435, subclass 6, for example.

VIII. Claims 42-46, drawn to a method for detecting a biological molecule, comprising: contacting a biological molecule with a reagent, said reagent comprising a nucleic acid portion and a portion that is capable of forming a specific complex with the biological molecule to form a detection mixture; contacting the detection mixture with a nucleic acid binding protein comprising a detection molecule, wherein the nucleic acid binding protein specifically binds to the nucleic acid portion of the reagent; and determining the presence or absence of the detection molecule in the detection mixture, wherein presence of the detection molecule correlates to presence of the biological molecule and absence of the detection molecule correlates to absence of the biological molecule, classified in class 435, subclass 6, for example.

IX. Claims 67, 68, drawn to a method of juxtaposing a Ter site on a nucleic acid molecule with a second site on the nucleic acid molecule, comprising: providing a nucleic acid molecule having a Ter site; contacting the nucleic acid with a Ter-binding protein in functional association with an enzyme capable of translocating along the nucleic acid molecule; and conducting a reaction that causes the enzyme to translocate, thereby juxtaposing the Ter site and the second site, classified in class 435, subclass 7.1, for example.

X. Claim 69, drawn to a method of cloning, comprising; providing a linear vector comprising a portion of a Ter site on each end; ligating a nucleic acid of interest with the vector to form a ligation mixture, wherein vectors that do not ligate with a nucleic acid reform a functional Ter site; and introducing the ligation mixture into host cells, wherein host cells that receive a vector with a functional Ter site do not replicate the vector, classified in class 435, subclass 6, for example.

XI. Claims 70-82, 86, drawn to a method for synthesizing a double stranded nucleic acid molecule comprising all or a portion of one or more Ter sites, comprising: (a) mixing one or more nucleic acid templates with a polypeptide having polymerase activity and one or more primers comprising all or a portion of one or more Ter sites; (b) incubating said mixture under conditions sufficient to synthesize a first nucleic acid molecule which is complementary to all or a portion of said templates and which comprises said all or portion of one or more Ter sites; and (c) incubating said first nucleic acid molecule in the presence of one or more primers under conditions sufficient to synthesize a second nucleic acid molecule complementary to all or a portion to said first nucleic acid molecule, thereby producing a double stranded

nucleic acid molecule comprising all or a portion of one or more Ter sites, classified in class 435, subclass 91.2,. for example.

XII. Claims 83-85, drawn to a method for adding one or more Ter sites or portions thereof to one or more nucleic acid molecules, said method comprising: (a) contacting one or more nucleic acid molecules with one or more integration sequences which comprise one or more Ter sites or portions thereof; and (b) incubating said mixture under conditions sufficient to incorporate said integration sequences into said nucleic acid molecules, classified in class 435, subclass 6, for example.

XIII. Claim 87, drawn to a method for synthesizing one or more nucleic acid molecules comprising all or a portion of one or more Ter sites, said method comprising: (a) obtaining one or more linear nucleic acid molecules; and (b) contacting said molecules with one or more adapters which comprise one or more Ter sites or portions thereof under conditions sufficient to add one or more of said adapters to one or more termini of said linear nucleic acid molecule, classified in class 435, subclass 6, for example.

XIV. Claims 91-97, drawn to a method of cloning two DNA fragments into one vector in one reaction, wherein said vector comprises two markers for negative selection, said method comprising: replacing a first marker for negative selection with a first DNA fragment; in the same reaction mixture, replacing a second marker for negative selection with a second DNA fragment; and transforming host cells that are not resistant to either negative selection, classified in class 435, subclass 6, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to products with different structures, properties and functions. In the instant case, the product of Group I is a nucleic acid, whereas the product of Group II is a protein which is not encoded by the nucleic aid of Group I. Therefore searching for the products of Groups I and II together would constitute an undue burden on the examiner, as the searches are not coextensive.

3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to products with different structures, properties and functions. In the instant case the product of Group I is an isolated nucleic acid molecule comprising all or a portion of at least two Ter sites, whereas the product of Group III is an oligonucleotide comprising all or a portion of a single Ter site bound to a solid support. Therefore searching for the products of Groups I and II together would constitute an undue burden on the examiner, as the searches are not coextensive.

4. Inventions I and (IV-VII, IX and X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid of Group I can be used in an entirely different method, such as studies of DNA replication of bacteria, rather than in the methods of Groups IV-VII, IX and X.

5. Inventions I and (VIII and XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the invention of Group I is not required in the methods of Groups VIII and XIV.

6. Inventions I and (XI-XIII) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acid of Group I can be made by an entirely different method, such as chemical synthesis, rather than by the methods of Groups XI-XIII.

7. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to to products with different structures, properties and functions. In the instant case the product of Group II is protein, whereas the product of Group III is an oligonucleotide comprising all or a portion of a single Ter site bound to a solid support. Therefore searching for the products of Groups II and III together would constitute an undue burden on the examiner, as the searches are not coextensive.

8. Inventions II and (IV, VIII and X-XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the invention of Group II is not required in the methods of Groups IV, VIII and X-XIV.

9. Inventions II and (V-VII and IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the protein of Group II can be used in an entirely different method, such as studies of DNA replication of bacteria, rather than in the methods of Groups V-VII and IX.

10. Inventions III and (IV-XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the invention of Group III is not required in the methods of Groups IV-XIV.

11. Inventions IV-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to methods with different goals, method steps, and materials. Therefore searches for all of these methods together would constitute an undue burden on the examiner, as the searches are not coextensive.

12. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

13. This application contains claims directed to the following patentably distinct species:

Group I

Species of Ter sites

Please select one from the sites listed in claim 2.

Species of recombination sites

Please select one listed from the one listed in Table 3.

Species of a Ter-binding protein

Please select one sequence from Tables 5-14.

Species of the nucleic acid

Please select one from pTER1, pTER2 and pTER3 (claim 98).

Group II

Species of protein modification

A) modification comprises GFP (claim 14, in part),

B) modification comprises alkaline phosphatase (claim 14, in part),

C) modification comprises horseradish peroxidase (claim 14, in part),

D) modification comprises beta-galactosidase (claim 14, in part),

E) modification comprises luciderase (claim 14, in part),

F) modification comprises beta-glucuronidase (claim 14, in part),

G) modification comprises a label (claim 15).

Species of a Ter-binding protein

Please select one sequence from Tables 5-14.

Species of a support

H) a bead (claim 50),

I) a chromatography medium (claim 51),

J) a filter or membrane (claim 52).

Group III

Species of Ter sites

Please select one from Table 4.

Group IV

Species of a Ter-binding protein

Please select one sequence from Tables 5-14.

Group V

Species of a Ter-binding protein

Please select one sequence from Tables 5-14.

Group VIII

Species of a detection molecule

A) please select one from claim 45, or

B) please select one from claim 46.

Group XI

Species of Ter sites

Please select one from Table 4.

Group XII

Species of integration sequences

Please select one from claim 84.

The species are independent or distinct because the different Ter binding sites have different sequences and binding properties; the recombination sites have different sequences and binding properties; the Ter-binding proteins have different amino acid sequences and properties; the nucleic acids comprising Ter sites have different sequences; the proteins modifying the Ter-binding

proteins have different structures and functions; the supports have different properties and structures; detection molecules have different structures and functionalities; the integration sequences have different structures and properties.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the sets of species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 10, 20, 23, 28, 37, 42, 47, 53, 80, 83 and 88 aregeneric.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
8/18/07